APPLICATION AS AMENDED

METHOD AND APPARATUS FOR PROVIDING INVENTORY CONTROL OF MEDICAL OBJECTS

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to inventory control systems, and more particularly to a method and apparatus for providing inventory management and control of sutures, needles, lap pads, sponges and other medical objects within a sterile operating room environment.

Description of the Prior Art

Advances in medical technology in recent years have resulted in substantial improvements in patient care, often with reduced hospital stays and related costs. New devices and techniques, such as computer axial tomography (CAT) and balloon angioplasty, have reduced or even eliminated the need for some surgical procedures. In addition, new types of drugs and other treatments have further reduced the need for invasive procedures and long hospital stays.

However, when surgery or other invasive medical procedures are required, the sterile operating room and its accompanying procedures assume a central role in the treatment. Within the operating room

environment, large amounts of equipment, supplies and personnel are required for providing treatment. The supplies often include large numbers of sterile objects which are small and difficult to keep track of, particularly during long, complicated and tedious surgical procedures, and are at risk of being lost in the surgical wound with negative medical and liability consequences.

In preparation for a typical surgical procedure, large numbers of these objects such as needles, sutures, scalpel blades, lap pads, 4X4 sponges, cottonoids, peanut sponges, clamps and other instruments must be counted. This counting is usually done by the scrub nurse while the objects are being unpackaged and positioned on trays on the operating room sterile field. As the package for each object is opened, the object is manually counted by the nurse. A second "circulating" nurse verifies the count when the objects are shown to her by the scrub nurse.

During the surgical procedure, these objects are manually accounted for as they are used. For example, used needles and scalpel blades are placed in special open containers that are red in color to indicate biological waste. A manual hand count of these objects is then done at the conclusion of surgery, after which the containers are closed and then discarded. Similar manual counting procedures are used for soft objects such as lap pads and sponges. Reusable objects such as clamps and

forceps are counted and placed in other containers or instrument trays for cleaning and resterilization.

Near completion of the surgery, all objects are again manually counted, usually prior to closure of the wound. If this count does not correspond to the initial count, the operating room and wound are searched for the missing object. Eventually, if the object is not found and the count is not reconciled, radiological studies are used to determine whether the missing object has been left in the wound. If so, the wound is reexplored; if not, the original count is assumed to have been in error.

In addition, in the traditional operating room, a sharp object such as a suture needle is handled many times. The circulating nurse opens the outer wrapper of a suture package and flips the sterile inner package onto a sterile back table or Mayo stand while a scrub nurse watches. The scrub nurse then opens the sterile inner package, grasps the suture needle with a needle holder, pulls the coiled needle and suture from the package, and may then hand the needle holder to the surgeon or place it on the sterile Mayo stand for later use.

When requested by the surgeon, the loaded needle holder is handed to the surgeon by the scrub nurse. The surgeon passes the needle through the tissues to be sutured, knots the ends of the suture, cuts the suture at the knot with a scissor, and hands the needle holder containing the used needle back to the scrub nurse. The scrub nurse places the used

needle on a plastic or magnetic needle tray for subsequent manual counting. Toward the end of the surgery, the scrub nurse manually counts all of the used needles at least twice with the circulating nurse observing the counting. If the counts are correct, at the end of the surgery the scrub nurse discards the used needles into a red sharp disposal container.

Accordingly, there is a need for a method and apparatus for providing a more reliable and easier inventory control of medical objects within the sterile operating room environment, which eliminates the error-prone and time consuming manual counting methods, which can be used with existing medical inventory control systems, and which reduces the need for frequent handling of sharp objects, such as needles and scalpel blades, by medical personnel.

SUMMARY OF THE INVENTION

The preferred embodiments of the present invention are directed to a method and apparatus for providing inventory control of medical objects within a sterile operating room environment. The method and apparatus of the preferred embodiments of the present invention eliminate the disadvantages of conventional time consuming and error-prone manual counting methods, while reducing the frequency of handling of sharp objects, such as needles and scalpel blades, by a factor of four or more.

A goal of the preferred embodiments of the present invention is to save time by eliminating the tedious manual counting procedures now in use for counting sutures, needles, scalpel blades, sponges, lap pads and other

instruments and objects. Another goal is to substantially reduce the amount of handling of sharp instruments and objects which have been contaminated by blood or other biological fluids. Overall, the preferred embodiments of the present invention increase the efficiency of the inventory control procedures within the operating room environment.

The preferred embodiments of the present invention preferably use laser or other optical, magnetic, ultrasonic or radiological scanning technologies to manage the inventory of critical objects in the operating room environment. Specifically, one or more types of scanning and counting devices are used to determine the quantity and/or identity of each object that will be taken into the sterile operating room environment. Of particular concern are objects which are at risk of being lost in wounds, such as sponges, lap pads, pledgets, peanut sponges, cottonoids, needles and clamps.

According to the preferred embodiments of the present invention, an initial, preoperative count for such critical operating room objects is performed by preoperative scanning of such objects by the circulating nurse. In this scanning process, the circulating nurse preferably uses one or more of the scanning and counting devices mentioned above.

During and after the operation, many of the critical objects are scanned and then discarded. Other critical objects are placed on a tray or other suitable surface for postoperative scanning. Intraoperative and postoperative scanning of all initially scanned objects is automatically

reconciled at the end of the surgical procedure, instead of being performed manually by several surgical personnel.

In a first preferred embodiment of the present invention, a sterile self-contained disposable sharp object container is fitted with a counter/LED display mechanism. The counter/LED display mechanism is preferably mounted onto the collar of the disposable container. During and after surgery, used objects are placed in the disposable container by passing them through the counter/LED display mechanism which maintains a running count of the number of objects placed in the container. At the end of the surgical procedure, the counter/LED mechanism is removed from the disposable container and the disposable container is then sealed and discarded in the usual manner as contaminated medical waste.

Power to the counter/LED mechanism may be provided via a sterile disposable lead such as used with a Bovie cord or may be provided by an internal power source such as a battery.

A second preferred embodiment of the present invention includes an apparatus capable of determining and maintaining both a running count and the specific identity of each object placed in the disposable container. This capability requires that each surgical object be marked with an identifying code, such as a bar code, and is most useful for keeping track of hard, sharp objects including needles and scalpel blades and other hardware. This apparatus provides more complete inventory control data, as opposed to the generic counting provided in the first preferred embodiment.

For example, the inventory control of various sizes and/or types of screws, bolts, plates and other hardware used in orthopedic surgery may be improved by coding and scanning each item prior to surgery. This scanned data can be transmitted directly to the hospital inventory control system or to the appropriate product vendor for automatic reordering.

In a third preferred embodiment of the present invention, a handheld laser scanner provides the basic method of initial object counting, both inside or outside the sterile operating room environment. Needles, scalpel blades, sponges, pads and other objects are preferably lined up on a sterile magnetic receptacle or tray and the number of each type of object is scanned into the system. This preferred embodiment can be used for both generic and specific counting, depending on the type of object and coding system.

A fourth preferred embodiment of the present invention includes a fixed scanning device having a slot through which objects may be passed through for pre-operative or post-operative scanning. Individual objects, such as packaged sutures or scalpel blades, are passed through the slot for pre-operative counting. Similarly, groups of objects, such as lap pads, sponges or cottonoids may be fixed to a reusable holder and passed through the slot as a group for pre-operative counting. The same disposable holders for used lap pads, sponges or cottonoids likewise facilitate post-operative scanning by passage through the slot.

In a fifth preferred embodiment of the invention, a scale (not shown) for determining the weight of blood or other fluid loss in sponges and lap pads occurring during the surgical procedure may be included. This data can then be made available to a conventional anesthesia or hemodynamic data system under the supervision of the anesthesiologist.

Each preferred embodiment of the present invention preferably further includes a computer-based data collection system. The output from each counting or scanning device is transmitted to the data collection system for inventory management and control. The data collection system, which preferably comprises a conventional database management program, helps to insure that all objects which enter the sterile operating room environment are accounted for in the initial and final counts. The data collection system also minimizes the handling of sharp objects by eliminating most of the manual interim counts. Accordingly, the number of accidental cuts or sticks and the time spent searching for lost objects is significantly reduced. Moreover, the costs involved in extra anesthesia and operating room time can also be reduced, along with the time and expense of additional radiological studies used to determine the presence or absence of objects left in the wound.

The preferred embodiments of the present invention further include a method for counting and keeping track of all medical objects which enter the sterile operating environment. A method according to a preferred

embodiment of the present invention provides a fully integrated approach to the inventory management of medical objects within the operating room.

Further features and advantages of the present invention will be appreciated by a review of the following detailed description of the preferred embodiments taken in conjunction with the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be best understood by referring to the following detailed description of the preferred embodiments and the accompanying drawings, wherein like numerals denote like elements and in which:

Fig. 1 is a functional block diagram of an apparatus 100 for providing inventory control of medical objects, constructed in accordance with a preferred embodiment of the present invention;

Fig. 2 is a plan view of a conventional operating room 200, showing specific sterile and non-sterile fields that are relevant to the preferred embodiments of the present invention;

Fig. 3 is a perspective view of a device 300 according to a preferred embodiment of the present invention for counting and storing sharp medical objects such as needles and scalpel blades;

Fig. 4 is a side elevation of device 400 according to a preferred embodiment of the present invention, showing a sterile disposable receptacle for capturing medical objects;

Fig. 5 is a perspective view of a device 500 according to a preferred embodiment of the present invention for counting medical objects which are marked with a bar code or other identifying marking;

Fig. 6 shows the packaging for a conventional medical suture 600 which includes a bar code for use with the device of Fig. 5;

Fig. 7 is a top view of a magnetic storage strip 700 for holding used needles and sutures for post-operative counting in accordance with the preferred embodiments of the present invention;

Fig. 8 is a top view of a magnetic storage strip 800 for holding used scalpel blades for post-operative counting in accordance with the preferred embodiments of the present invention;

Fig. 9 is a top view of a storage strip 810 for holding used soft medical objects such as lap pads or sponges;

Fig. 10 is a side view of storage strip 810 of Fig. 9;

Fig. 11 is a flowchart 900 showing the steps of a method according to a preferred embodiment of the present invention for providing inventory control of medical objects; and

Figs. 12a-c show flowcharts of the steps of a method for reconciling the pre-operative and post-operative counts of the method of Fig. 9.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The following exemplary discussion focuses on a method and apparatus for providing inventory control of medical objects within a sterile operating room environment. The method and apparatus of the preferred

embodiments of the present invention eliminate the errors prevalent in manual counting methods that are currently in use, while simultaneously reducing the frequency of handling of sharp objects, such as needles and scalpel blades, by a factor of four or more.

Referring to FIG. 1, a functional block diagram of an apparatus 100 for providing inventory control of medical objects, constructed in accordance with a preferred embodiment of the present invention, is shown. In the preferred embodiment, apparatus 100 preferably includes a computer system 103 comprising a central processing unit (CPU) 104, a random access memory (RAM) 102, a software database 108 and a network interface 106. CPU 104 and RAM 102 are used to process and temporarily store computer program instructions for counting and tracking medical objects within the sterile operating room environment. Database 108 preferably comprises a conventional database management program such as MICROSOFT ACCESS software (available from Microsoft Corporation, One Microsoft Way, Redmond, Washington 98006), which provides non-volatile storage and management of the data relating to the counting and tracking of the medical objects. The storage provided by database 108 is called "nonvolatile" because the database is maintained even after the power to computer system 103 has been removed.

Network interface 106 provides the ability to connect computer system 103 to other computer and information systems through a local or wide area network, for example. This connection ability allows apparatus

100 to form a part of a larger medical inventory control and management system. For example, apparatus 100 may be connected to a conventional materials requisition and planning (MRP) system so that the numbers and types of objects may be closely tracked and automatically re-ordered as necessary.

Apparatus 100 further includes a data acquisition sub-system 110 and multiplexer 112 for receiving and processing data received from one or more transducers 114-122. The data acquisition sub-system 110 and multiplexer 112 may preferably comprise known electronic hardware and software capable of receiving, processing and transmitting signals to the CPU 104 as is known in similar input/output interface and signal processing devices.

In the preferred embodiment, transducers 114-122 may include optical, magnetic, ultrasonic or radiological devices or other suitable data obtaining devices for scanning each medical object and generating an electrical signal which encodes the identity of each scanned object. Transducers 114-122 may be embodied in known handheld scanning devices such as a laser scanning gun. Alternatively, the transducers may be embodied in the scanning devices shown in Figs. 3-5 or other suitable known scanning devices. Each electrical signal generated by the transducers 114-122 is communicated to multiplexer 112 which, in turn, transmits each electrical signal to data acquisition sub-system 110 where the signals are

preferably converted to digital form and transferred to computer system 103 for decoding and storage in database 108.

A typical operation of apparatus 100 involves the scanning of critical surgical objects including preoperative, intraoperative and postoperative scanning using transducers 114-122. The signals generated by transducers 114-122 preferably include either a simple count information (one object scanned) or also include identification information for each object scanned. Each of the signals will include information regarding whether the object scanned is part of a pre-operative, intraoperative or post-operative count process. The signals generated by transducers 114-122 are transmitted to data acquisition subsystem 110 via multiplexer 112. After the signals are stored in the database 108 as described above, the data resulting from the signals is ready for use. As will be described in the following paragraphs, upon completion of a surgical procedure, computer system 103, using appropriate software stored therein, will determine if the initial object count and the postoperative object count match, thereby eliminating any manual counting or matching of preoperative and postoperative counts. In addition, as described below, computer system 103 may identify the missing object or objects after determining that the initial object count and postoperative object count do not match.

Referring now to FIG. 2, a plan view of a conventional operating room 200, showing specific sterile and non-sterile fields that are relevant to the preferred embodiments of the present invention is shown. The sterile fields

of operating room 200 include sterile trays 202 and 204, Mayo stands 206 and 208, and operating table 210. The non-sterile fields of operating room 200 may include storage cabinet 212 and desk 214. In fact, a large portion of operating room 200 is not required to be sterile.

Any objects which come in contact with any of sterile fields 202-210 must first be sterilized. For example, needles, sutures, scalpel blades, lap pads, sponges and cottonoids are typically provided in sterile packages which are opened using procedures which maintain the sterility. Similarly, all instruments, electrical cords, sheets and drapes are also sterilized prior to being introduced into any of the sterile fields.

FIG. 3 shows a perspective view of a first preferred embodiment of a device 300 for counting and storing sharp medical objects such as needles and scalpel blades for use with apparatus 100 shown in Fig. 1. Device 300 includes a self-contained disposable sharp object container 304 that is preferably fitted with a visible counter/LED display mechanism 302. Container 304 preferably comprises a conventional red plastic container which is used to dispose of biologically contaminated waste. Counter/LED display mechanism 302 preferably comprises an array of sensors 306 provided within a circular collar and an internal counter (not shown) for counting the objects sensed by the sensors 306. The sensors 306 correspond to one or more transducers 114-122 of Fig. 1. The internal counter in counter/LED display mechanism 302 is preferably connected to multiplexer 112 and data acquisition subsystem 110 via a sterile disposable

electrical cord 310 or other suitable signal transmitting device such as an infrared connector to provide object count information to computer system 103. Counter/LED display mechanism 302 may preferably be powered via an internal power source such as a battery or may be connected to an external power source via a sterile electrical cord not shown.

Counter/LED display mechanism 302 also preferably includes a display preferably including a light emitting diode (LED) display 308 for indicating a number of discarded objects. Counter/LED display mechanism 302 also preferably includes a reset button 309 for resetting the count indicated on display 308.

Counter/LED display mechanism 302 is preferably mounted onto the collar of disposable container 304. During and after surgery, used sharp objects, such as needles and scalpel blades, are placed in disposable container 304 by dropping them through counter/LED display mechanism 302. Sensors 306, corresponding to one or more transducers 114-122, sense each object being dropped into container 304. Sensors 306 are electrically connected to counter/LED display mechanism 302 such that the internal counter in counter/LED display mechanism 302 counts each object sensed by sensors 302 and maintains a running count of the number of objects placed in container 304. Additionally, counter/LED display mechanism 302 may contain an indicator device (not shown) such as a visual indicator in the form of a flashing light, for example, or an audible indicator in the form of a sound generating device to generate an audible

"beep" or similar tone each time an object is dropped into disposable container 304.

During the surgical procedure, counter/LED display mechanism 302 maintains a count of each object discarded into container 304 and transmits this count as a post-operative count to computer system 103 via multiplexer 112 and data acquisition subsystem 110. At the end of the surgical procedure, counter/LED mechanism 302 is removed from disposable container 304. Then disposable container is sealed and discarded according to established procedures for the disposal of biologically contaminated materials.

It is not necessary that counter/LED display mechanism 302 be connected to computer system 103. Counter/LED display mechanism 302 may be independent of the computer system 103 and used by personnel in the operating room to compare the count of initial objects stored in computer system 103 with a final count displayed on counter/LED display mechanism 302.

Continuing with FIG. 4, a side elevation of device 400 for counting and storing sharp medical objects is shown. Device 400 is similar to device 300 shown in Fig. 3 and is preferably connected to computer system 103 via a sterile cable 410. Device 400 also includes a reset button 409 and a counter/LED display mechanism 402. In FIG 4, counter/LED display mechanism 402 includes a sterile disposable receptacle 412 for guiding objects through the collar of counter/LED display mechanism 402 and into

disposable container 404. In addition to providing an effectively larger opening for container 404, sterile receptacle 412 further reduces the risk of contamination of surgical instruments, such as needle holders or scalpel handles, with which it may come in contact.

Device 400 provides both a running count along with the specific identity of each object placed in disposable container 404. To do so, sensors (not shown) similar to sensors 306 in Fig. 3 or transducers 114-122 preferably comprise known data or optical character reading devices such as laser bar code readers or optical scanners which are capable of reading bar codes or other identification indicia contained on the objects to be counted and identified. Obviously, in order for the sensors or transducers 114-122 of device 400 to identify each object, each object must be marked with an identifying code, such as a bar code. Device 400 having object identification ability is most useful for hard, sharp objects including needles and scalpel blades and other hardware. Device 400 can thus provide more complete inventory control data, as opposed to generic counting.

For example, the inventory control of various sizes and/or types of needles, screws, bolts, plates and other hardware used in orthopedic surgery may be improved by coding and scanning each item prior to surgery. This scanned data can be transmitted directly to the hospital inventory control system or to the appropriate product vendor for automatic reordering.

Referring to FIG. 5, a perspective view of a second preferred embodiment of a device 500 for specifically scanning medical objects which are marked with a bar code or other identifying nomenclature is shown. Scanning device 500 has a slot 507 having a sensing device 508 through which objects may be passed through for scanning. Packaged objects, such as sutures or scalpel blades, are passed through slot 507 for counting. Alternatively, groups of objects, such as lap pads, sponges or cottonoids may be fixed to a holder or rack and passed through slot 507 as a group for counting.

Scanning device 500 also preferably includes an LED display 504 for displaying the total number of objects counted, along with a button 506 for resetting LED display 504. Additionally, scanning device 500 may generate a visual indicator or an audible indicator such as a beep or similar tone each time an object is passed through slot 507 and detected by sensing device 508, similar to the alarm system described with reference to the preferred embodiment shown in Fig. 3.

FIG. 6 shows a typical packaged medical object 600, such as a needle or suture, which may be counted using scanning device 500 or counting device 400 of Fig. 4. In the preferred embodiment, packaged object 600 is imprinted with a bar code 604 or other identifying nomenclature which may be scanned. Package 602 is passed through slot 507 where bar code 604 is read by sensing device 508, and a visual signal or an audible beep may be generated when bar code 604 has been successfully read.

Alternatively, a conventional hand-held laser scanner (not shown) may provide the basic method of object scanning, both inside or outside the sterile operating room environment. Packages of needles, scalpel blades, sponges, pads and other objects are lined up on a sterile magnetic tray and the number of each type of object is scanned into the system. This preferred embodiment can be used for both generic and specific counting, depending on the type of object and package coding system. The conventional hand-held scanner can be connected to computer system 103 for transmitting count information to computer system 103. Alternatively, the conventional hand-held scanner can store count information locally on a computer disk or other data storage device, and then the computer disk or other data storage device can interface with computer system 103 to transfer the count information thereto.

As shown in FIGS. 7 and 8, individual sharp objects such as needles 702 and scalpel blades 802 may be positioned on trays 700 and 800 for scanning prior to disposal. Trays 700 and 800 may then be scanned either by scanning device 500 or by a conventional hand-held laser scanner. Similarly, used soft objects such as lap pads, sponges and cottonoids may also be positioned on disposable holders for scanning prior to disposal. In both cases, disposal is accomplished using established methods for biological waste.

Continuing with FIGS. 9 and 10, soft objects such as lap pads, sponges and cottonoids may be positioned on a flexible storage strip 810

for counting. In FIG. 9, a number of lap pads 812-822 are positioned on storage strip 810 using the "tails" 824-834 of each pad. Each of the tails 824-834 is typically designed to be radio-opaque so that they are visible under x-ray or similar scanning device.

FIG. 10 shows a side view of lap pad 812 as it is secured to storage strip 810 by tail 824. Storage strip 810 is bowed to provide tension to tail 824 and to thus make scanning easier.

Referring now to FIG. 11, a flowchart 900 showing the steps of a method for providing inventory control of medical objects, in accordance with the preferred embodiments of the present invention, is shown. The method shown in Fig. 11 is preferably performed using apparatus 100 shown in Fig. 1 and one or more of devices 300, 400, 500 or other appropriate scanning devices.

Processing begins with step 902 and continues with step 904 in which a first pre-operative count of each object to be taken into the operating room is performed. The first pre-operative count is preferably performed by the scrub and circulating nurses using scanning devices such as transducers 114-122, a hand-held laser scanning device or other suitable scanning devices to establish an initial count, and possibly identification, for each object to be taken into the operating room. As mentioned previously, the signals generated by the scanning devices include an indicator that a pre-operative count or a post-operative count is being performed. This information can be incorporated in the signals using appropriate software

and hardware in the computer system 103 and/or scanning devices. Processing continues with step 906 where the soft objects, such as lap pads and sponges, are preferably separated from the hard objects, such as instruments, needles and scalpel blades.

Processing continues with step 908 in which the soft objects may be weighed to provide a basis for determining blood and other fluid loss which may occur during the surgical procedure. During and after the surgical procedure, processing continues with step 910 in which the soft objects are placed on disposable racks for the first post-operative count. The first post-operative count is performed at step 912 using a first electronic scanning device (which may be the same device as used for the pre-operative count as described above or may be another suitable device such as devices 300, 400, 500). Additionally, at step 914 the post-operative weight of the soft objects may also be performed.

For the hard objects, processing during and after the surgical procedure continues at step 916 where the surgical instruments are separated from the disposable objects. For the surgical instruments, processing continues at step 918 in which the instruments are electronically counted by device 300, 400, 500 or some other suitable scanning device. For the disposable objects, processing continues at step 920 in which the objects are further separated into those which are stored in disposable containers and those which are lined up on trays for counting. For the objects that are stored in disposable containers, processing continues at

step 922 in which each object is scanned as it is placed in the container. For objects which are lined up on trays for counting, processing continues at step 924 in which the objects are lined up on the trays and then counted by scanning such objects using one of the scanning instruments mentioned above.

For all objects, processing continues at step 950 in which the pre-operative and post-operative counts are reconciled, which process is described in more detail with reference to Figs. 12a-12c in the following paragraphs.

Processing then ends at step 968.

Referring to FIGS. 12a-12c, a flowchart 950 showing the reconciliation of the pre-operative and post-operative counts is shown. Processing begins at step 952 and continues at step 954 in which a comparison of the pre-operative and post-operative counts is made. If the counts match, processing ends at step 968. If the counts do not match, processing continues at step 956 in which a second post-operative count is performed using a second electronic scanning device, the latter which is preferably different from the scanning device used in steps 912, 922 and 924.

Processing then continues at step 958 in which the results of the second count and the pre-operative count are compared. If the counts match, processing ends at step 968. If the counts do not match, processing continues at step 960 in which a search of the wound and operating room is performed.

Processing then continues at step 962 in which the results of the search and the pre-operative count are compared. If the counts match, processing ends at step 968. If the counts do not match, processing continues at step 964 in which a radiological or ultrasound examination of the wound is performed.

Processing then continues at step 966 in which a determination of the results of the radiological or ultrasound examination of the wound is made. If the missing object has been found, processing continues at step 990. If the object has not been found, processing continues at step 970.

If the missing object has not been found during the radiological or ultrasound examination, processing then continues at step 972 (FIG. 12b) in which a manual count of the medical objects is performed. Processing continues at step 974 in which the results of the manual count and the pre-operative count are compared. If the counts match, processing ends at step 968. If the counts do not match, processing continues at step 976 in which the pre-operative count is assumed to have been in error.

Processing continues at step 978 in which an incident report regarding the error is documented. Processing then ends at step 968.

If the missing object has been found during the radiological or ultrasound examination, processing then continues at step 994 (FIG. 12c) in which the wound is manually re-explored for the purpose of retrieving the object. Processing continues at step 996 in which the results of the manual re-examination are determined. If the missing object has been found,

processing ends at step 968. If the missing object has not been found, processing continues at step 998 in which an incident report documenting the type and location is prepared. Processing then ends at step 968.

In the foregoing description of the method shown in FIGS. 11-12c, it is possible to not only compare pre-operative and post-operative counts of objects, it is also possible to receive, store and compare detailed information regarding the number and types of objects used during the surgical procedure. This information can be used to readily identify an object that has not been accounted for during the post-operative inventory scanning procedure. In addition, the detailed information regarding the number and types of objects used during the surgical procedure can also be used in appropriate inventory control, materials requisition planning or similar systems.

In order to implement this preferred embodiment, the scanning devices capable of reading bar code or other printed indicia described with reference to FIGS. 4-6 and other known optical character recognition devices are preferably used. The objects to be used during the surgical procedure are scanned to generate information regarding the pre-operative count and also pre-operative inventory of objects to be used, including detailed information regarding the identity and type of each object scanned. This operation may be performed at step 904 as shown in FIG. 11.

During the surgical procedure, as objects are discarded into containers such as that shown in FIG. 4, the count and detailed information

regarding the type of object being discarded is read by the device 400 and transmitted to the computer system 103. A similar post-operative scanning is done of materials which are not discarded into containers such as those in FIG. 4. Such post-operative scanning is conducted at step 924 in FIG. 11.

During the step 950 in FIG. 11 of reconciling the pre-operative and post-operative counts, in this preferred embodiment, if the pre-operative and post-operative counts do not match, the CPU 104 and appropriate known inventory software compares the detailed information regarding the number and types of objects scanned during the pre-operative scan and during the post-operative scan to readily identify the exact type and number of object or objects which are missing after the post-operative scan. Thus, this provides the surgical team with detailed information regarding the exact type and number of objects which may be missing or were incorrectly scanned.

In each of the steps of reconciling the pre-operative and post-operative scanning processes, the computer system 103 may be programmed to provide an alarm or indication, either visual, audio or otherwise, to indicate that there is no match between the post-operative and pre-operative scan and to provide detailed information about the number, type and identity of the missing objects. After such indication, the processing as shown in FIGS. 11-12c may continue until either a match occurs or an incident report is generated.

The combination of apparatus 100, one or more of devices 300, 400, 500 or other scanning devices and the method represented by flowchart 900 thus comprise a complete computer-based inventory and data collection system. The data collection system helps to insure that all objects which enter the sterile operating room environment are accounted for in the initial and final counts. The data collection system also minimizes the handling of sharp objects by eliminating most of the manual interim counts. Accordingly, the number of accidental cuts or sticks and the time spent searching for lost objects is significantly reduced. Moreover, the costs involved in extra anesthesia and operating room time can also be reduced, along with the time and expense of additional radiological studies used to determine the presence or absence of objects left in the wound. Finally, the method represented by flowchart 900 may form a component of a larger system for standardizing and controlling surgical and operating room procedures.

The foregoing description includes what are at present considered to be preferred embodiments of the invention. However, it will be readily apparent to those skilled in the art that various changes and modifications may be made to the preferred embodiments without departing from the spirit and scope of the invention. Accordingly, it is intended that such changes and modifications fall within the spirit and scope of the invention, and that the invention be limited only by the following claims.

What is claimed is:

1. (twice amended) An apparatus for providing inventory control of medical objects, said apparatus comprising:

a scanner for scanning each of said medical objects before and after a surgical procedure and generating a signal each time one of said medical objects is scanned, the scanner generating data as to a type of medical object to be used for identifying the medical object later, said data being included in said signal;

a container adapted for storing said medical objects after use, said container having an opening for receiving said medical objects and at least one sensor for sensing said medical objects upon insertion into said container, said at least one sensor being removably coupled to said opening;

a counter for receiving said signal from said scanner and determining a first count of said medical objects before said surgical procedure and a second count of said medical objects after said surgical procedure; and

a reconciling device for receiving said first count of said medical objects and second count of said medical objects from said counter and for comparing said first count and said second count to determine if said first count equal said second count and if the first count and second count are not equal, the reconciling device determining and identifying a type of medical object which is missing based on a difference between the first and second counts and based on the data as to the type of medical object, which data is included in said signal.

2. The apparatus of claim 1, wherein said scanner includes a reader for reading identification data contained on said medical objects.

3. (amended) The apparatus of claim 2, further comprising an identification device for receiving said identification data from said scanner and for identifying an object type of each of said medical objects scanned by said scanner, said reconciling device receiving said identification data from said identification device and matching identification data received during said first and second counts of said medical objects to identify a type of one of said medical objects that was identified during said first count but was not identified during said second count.

4. The apparatus of claim 1, wherein said counter and said reconciling device comprise a computer system including a memory for storing said first and second counts.

5. (amended) The apparatus of claim 1, wherein said counter and said reconciling device comprise a computer system including a memory for storing said first and second counts of said medical objects.

7. (amended) The apparatus of claim [6] 1 wherein said container further comprises an internal counter connected to said sensor for counting said medical objects received in said container.

8. The apparatus of claim 7, wherein said internal counter is connected to said counter for transmitting count information to said counter.

9. (amended) The apparatus of claim 1, wherein said container includes an alarm mechanism connected to said at least one sensor for indicating when said at least one sensor senses one of said medical objects.

10. (amended) The apparatus of claim 1 wherein said container comprises a disposable jar for storing sharp objects including needles and scalpel blades and a light emitting diode display for providing a visual count of said medical objects.

17. (twice amended) A method for providing inventory control of medical objects used in a surgical procedure, said method comprising the steps of:

scanning and counting each of said medical objects before the surgical procedure to obtain a pre-operative count of said medical objects and data as to a type of each of said medical objects;

transmitting a signal including said pre-operative count and said data concerning a type of said medical objects to a computer system for storing said pre-operative count and said medical object type data;

scanning and counting each of said medical objects after the surgical procedure to obtain a post-operative count of said medical objects and data concerning a type of each of said medical objects;

providing a container adapted for storing said medical objects after use, said container having an opening for receiving said medical objects and at least one sensor for sensing said medical objects upon insertion into said container, said at least one sensor being removably coupled to said opening;

transmitting said post-operative count and said data concerning a type of each of said medical object scanned in said post-operative scanning to the computer system for storing said post-operative count and said data concerning a type of each of said medical objects;

comparing said pre-operative count with said post-operative count for determining which of said medical objects are missing after said surgical procedure and if the first count and second count are not equal, determining and identifying a type of medical object which is missing based on a difference between the first and second counts and based on the data as to the type of medical object, which data is included in said signal; and

searching for said medical objects which are determined to be missing in said step of comparing.

18. The method of claim 17, wherein said steps of scanning and counting each of said medical objects before and after the surgical procedure includes the step of reading identification information contained on each of said medical objects.

19. The method of claim 17, wherein said step of comparing said pre-operative count and post operative count further comprises the step of providing notification of the results of said step of comparing.

20. The method of claim 17, further comprising the steps of:

pre-operatively weighing said medical objects to obtain a pre-operative weight;

post-operatively weighing said medical objects to obtain a post-operative weight;

and comparing said pre-operative weight with said post-operative weight for determining an amount of blood lost during said surgical procedure.

METHOD AND APPARATUS
FOR PROVIDING INVENTORY CONTROL OF MEDICAL OBJECTS

Abstract of the Disclosure

A method and apparatus for providing inventory management and control of sutures, needles, lap pads, sponges and other medical objects within a sterile operating room environment eliminates the tedious and error-prone manual counting methods, while reducing the handling of sharp objects, such as needles and scalpel blades, by a factor of four or more. In the method and apparatus, one or more types of scanning and counting devices are used to determine the quantity and/or identity of each object that will be taken into the sterile operating room environment. The scanning and counting devices are connected to a computer system which includes inventory control and networking programs to determine if the number and identity of each object initially provided for use in surgery is recovered or accounted for after surgery.

REMARKS

Claims 1-5, 7-10, and 17-20 are pending consideration on the merits. Applicant encloses herewith a petition to revive an unintentionally-abandoned application under 37 CFR 1.137(b) for the parent application US Serial No. 08/734,246 to this continuation application. Revival of the parent application is respectfully requested. The Examiner has made final the rejection under 35 USC § 103(a) of parent claims 1-5, 7-10, and 17-20 as being unpatentable over US Patent 5443082 ("the '082 patent") in view of US Patent 5993046 ("the '046 patent"). These remarks are prepared as a response to the final rejection made in the August 2, 2000 Office Action for the parent application as well to clarify issues remaining in this request for continuing examination.

A brief, non-limiting summary of the present invention is offered to assist the Examiner's comprehension of the features of the present invention and how these features distinguish the present invention from the prior art. The present invention is directed to a method and apparatus for providing inventory control of medical objects within a sterile operating room environment. Overall, the preferred embodiments of the present invention increase the efficiency of the inventory control procedures within the operating room environment. One aim of the preferred embodiments of the present invention is to save time by eliminating the tedious manual counting procedures now in use for counting sutures, needles, scalpel blades, sponges, lap pads, and other instruments and objects. Another goal is to reduce by a factor in excess of four the amount of handling of sharp instruments and objects which have been contaminated by blood or other biological fluids.

According to the preferred embodiments of the present invention, an initial preoperative count for objects which are at risk of being lost in wounds, such as sponges, lap pads, pledgets, peanut sponges, cottonoids, needles, and clamps, is performed by preoperative scanning of such

objects by a circulating nurse into one or more scanning mechanisms using laser or other optical, magnetic, ultrasound, or radiological scanning technology to determine the quantity and/or identity of each object to be taken into or used within the sterile operating room environment. This is desirable because during and after a surgical procedure, many of such critical objects are scanned, used, then discarded, while other critical objects may be placed into a container or other suitable surface for postoperative scanning. Instead of being performed manually by several surgical personnel, which increases the risk of faulty counts, accidental inclusion into the patient's body, and so on, intraoperative and postoperative scanning of all initially-scanned objects is automatically reconciled at the end of the surgical procedure.

In a first preferred embodiment of the present invention, a sterile self-contained disposable sharp object container is fitted with a counter/LED display mechanism, preferably mounted onto the collar of the container. Power to this mechanism may be provided via a sterile disposable lead or by an internal power source. Used objects are placed into the container during and after surgery by passing them through the counter/LED display which maintains a running count of the number of objects placed within the container. At the end of the surgery, the counter/LED mechanism is removed from the container, which is then sealed and discarded as contaminated medical waste.

A second preferred embodiment of the present invention includes an apparatus capable of determining and maintaining both a running count and the specific identity of each object placed in the disposable container. To achieve this, each surgical object is prelabelled with an identifying code, for example a bar code. This is most useful for keeping track of surgical hardware, such as various sizes and/or types of screws, bolts, plates, and other objects used in

orthopedic surgery. Further, this scanned data can be transmitted directly to the hospital inventory control system or to the appropriate product vendor for automatic reordering.

In a third preferred embodiment of the present invention, a handheld laser scanner provides the basic method of initial object counting, performed either inside or outside the sterile environment. Needles, scalpel blades, sponges, lap pads, and other instruments and objects are preferably lined up on a sterile magnetic receptacle, tray, or container, and the number of each type of object is scanned into the system. This method may retain both a running count and the specific identity of each object, depending on the type of object and coding system used.

In a fourth preferred embodiment of the present invention, a fixed scanning device has a slot through which individual objects, such as packaged sutures or scalpel blades, or groups of objects fixed to a reusable holder, such as lap pads, sponges, or cottonoids, are passed through the slot individually or in groups for preoperative counting. The reusable holder may also hold used lap pads, sponges, or cottonoids for postoperative scanning.

In a fifth preferred embodiment of the present invention, a scale for determining the weight of blood or other fluid loss in sponges or lap pads occurring during the surgical procedure may be included. This data can then be made available to a conventional anesthesia or hemodynamic data system under the supervision of the anesthesiologist.

Each preferred embodiment of the present invention preferably further includes a computer-based data collection system such that the output from each counting or scanning device is transmitted to a data collection system for inventory management and control. The data collection system, preferably comprising a conventional database management system, ensures that all objects which enter the sterile environment are accounted for in both initial and final counts. By eliminating manual interim counts, the data collection system minimizes the

handling of hazardous sharp objects and reduces the cost of expensive operating room time or extra radiological studies to determine the presence or absence of objects left within the patient.

For the reasons set forth below, Applicants urge that these claims are all in condition for allowance and respectfully request such issuance of a notice of allowance at the earliest possible date.

The '082 patent cited against the parent application generally claims a technique for controlling articles of equipment for use in surgery through automation of the counting and weighing procedures. In one embodiment, the '082 invention provides a system for controlling articles of equipment for use in surgery, comprising surgical equipment articles such as absorbent swabs, surgical instruments, which may be formed from metallic or non-metallic materials, and sutures, which individually and directly bear a machine-readable source of information, means for reading the information from each of the articles, and a computer connected to the reading means for recording information obtained from the articles. The information is applied directly onto the articles of equipment rather than to packets in which the articles are packaged before or after they are sterilized, thereby allowing the articles to be counted not only before but also after use in surgery. However, the system of the '082 invention may also be used to control articles of equipment which are contained in packets, by placing bar codes on the packets rather than directly on the articles themselves. Preferably the articles are opaque to X-rays, to facilitate location of such articles which have been left in a body cavity after surgery.

The machine-readable information source is preferably optically readable, such as a bar code, although other forms of information source such as radio responders and magnetic devices may be used. This invention includes means for weighing the articles of equipment, the

weighing means being connected to the computer so that information concerning the weight of the articles can be recorded on the computer. This system may be used to automatically calculate the weight of blood and other body fluids which are lost during surgery.

The system of the invention of the '082 patent may also include means for retrieving information from the computer, such as a monitor or a printer, and may also include auxiliary means for entering information into the computer, such as a keyboard to enter information concerning the patient or surgical equipment. Components of the system of the invention, other than the articles of equipment themselves, may be mounted on a trolley so that they can be easily moved from one location to another, for example between operating theaters.

The '046 patent cited against the parent application generally claims an apparatus and system for monitoring and dispensing medical items in hospital or clinic environments that can more accurately monitor inventories, dispense medical items and correlate the use of medical items with the patient whose treatment has included their use. This system includes a plurality of item storage locations, such that a particular type of medical item may be stored in each location. Each location in the system includes at least one unit of the particular type of medical item. A sensor particularly adapted to sense the addition or subtraction of a unit of the particular type of medical item stored in that location is positioned adjacent to each location. Thus, each time a unit of the particular item is added or removed from storage in the location, the sensor senses this and generates a signal. A counter is connected to each sensor and records the number of units added or removed from each location. The counter holds a count of the change in the number of units at the location since the last time the counter was read, and the counters associated with each location are connected to at least one processor and at least one memory or data store. The data store includes a total of the number of items that are located in storage at the location.

Periodically, the processor polls each of the counters and reads the change in the number of units stored therein; the processor is thereafter operative to update the total number stored in the memory to reflect the number of items currently stored at the location.

Embodiments of the invention of the '046 patent include a data terminal, connected to the processing system and the counters, which includes a user interface. The data store includes records concerning patients, procedures, authorized users of the system, and each of the products stored in each of the locations. The data store also includes correlated data concerning the brand names and generic names for medications and other medical items stored in the locations of the system, including pricing information. The data store further includes information on "kits," groups of medical items that are used together, either items which are used together repeatedly, such as in doing a diagnostic test, or items that are to be used on a onetime basis, such as for a particular patient's operative procedure.

A user, such as a technician or nurse, uses the interface of the data terminal to identify the particular patient who is to receive the medical items taken by the user. Upon removal or dispense of the items from the storage locations, the use of such items is recorded in the patient record in the data store so that the patient's chart may be automatically updated and the item charged. In addition, a user using the data terminal may review information in the data store concerning procedures and physicians to determine what medical items are required by a physician to conduct a procedure, and the user may remove such items for delivery to an operating room. This information may include kits which relate to particular procedures. The user is enabled to take or cause medical items to be dispensed through input to the data terminal. The user may also use the interface of the data terminal to check available stocks of medications, as well as medications which have been prescribed for a patient, by checking the brand name for

medical items designated by generic name, and vice versa. This is done by the user interface interfacing with the drug information stored in the data store. This also enables a user to check the appropriate character of an item prescribed by checking any other name. This also enables a user to determine the availability and use a brand name or generic name equivalent to the medical item prescribed, when the brand or generic type prescribed is not available.

In alternative embodiments of the invention of the '046 patent, controlled substances such as narcotics may be dispensed from a dispenser mechanism or an electronic lock drawer. In such embodiments, the user is required to identify himself at the display terminal. This information is processed and compared to authorized user records in the data store to verify that the user is an authorized user; a countersigning authority may be required here as well. The user's identifying information may be placed on an encoded object, such as a card, and the user may be assigned a personal identification number. In still other embodiments of the invention, the system may interface with other computer systems such as the admission-discharge-transfer computer system that the hospital uses to track patients.

The system of the present invention may also be connected to the hospital information system, or the record storage facility of the hospital which maintains computerized records concerning patients. The system may be interfaced to the pharmacy system which keeps records of medications prescribed for each patient. As a result, patient activity, record keeping, and billing may be automated through the system of the present invention, along with inventory monitoring. The system of the present invention may also be used to produce a wide variety of reports from the data store related to patients, authorized users, physicians and various types of items used in inventory. Such a system may also be integrated with an automatic ordering

system so as to transfer supplies from one location to another where they are needed and/or to automatically place orders for additional supplies with vendors when supply levels reach a limit.

The Examiner has acknowledged that neither the '082 patent nor the '046 patent individually claims the parent invention. For example, the '082 patent does not recite claims for a container in which surgical objects may be stored, said container having an opening for receiving said surgical objects and at least one sensor removably coupled to the opening for sensing said surgical objects upon insertion into the container. Furthermore, the '046 patent does not recite claims for a weighing means and method of preoperatively and postoperatively weighing surgical objects and comparing these weights to determine the amount of blood lost during a surgical procedure. *See* 08/734,246 August 2, 2000 Office Action, pages 3-4, 6.

However, the Examiner nevertheless rejected claims 1-5, 7-10, and 17-20 of the parent application under 35 USC § 103(a) as being unpatentable over the '082 patent in view of the '046 patent. This is because

> [i]t would have been obvious to one of ordinary skill in the art at the time of the invention to electrically connect the container as disclosed by [the '046 patent] to the apparatus control taught by [the '086 patent] to build apparatus as claimed because the combined apparatus would be suitable for monitoring inventory of medical objects of various types such medical equipment, supplies.

Id., page 4. For the reasons set forth below, the Applicant urges that these continuation claims are all in condition for allowance and respectfully request such issuance of a notice of allowance at the earliest possible date.

The Applicant respectfully urges that there are flaws in the rejection of the parent application. Turning to the '046 patent, Applicant notes the statement at page 3 of the subject Office Action that:

> [i]n the same field of endeavor [as the '086 patent], however, [the '046 patent] recites a container for storing medical objects after use (Figure 2, apparatus 10),

said container having an opening for receiving said medical objects (col. 6, Fig. 1 and 2 item 36, object support means) and least-one [sic] sensor for sensing said medical objects upon insertion into said container, said at least one sensor being removably coupled to said opening.

However, neither the specification nor claims of the '046 patent support this interpretation that the present invention has been rendered obvious in view of the '046 patent.

The "container" of the '046 patent referred to in the Office Action is actually a "dispenser" for instruments to be utilized in a surgical procedure or medical treatment. This dispenser simply stores the instruments prior to their use in the procedure or treatment, and the sensor is used to determine when a instrument is withdrawn from the dispenser. The apparatus 10 cited by the Examiner is described within the '046 specification thusly (drawing reference numerals deleted):

> Apparatus includes an elongated housing including an upper wall, a lower wall, side walls, a front wall and a rear wall. Housing may be formed of any suitable durable material such as plastic or metal. A clip assembly or similar attachment mechanism is desirably carried by a flange of rear wall whereby the housing may be detachably fastened to a rail or similar support structure affixed to a wall or like surface. . . .
>
> An object support means is designated. . .As illustrated, the object support may assume the form of an elongated rigid or angled rod which may be suitably formed of metal or plastic. A shorter leg of the object support means is affixed such as by threaded fasteners to the rear wall of housing. A longer leg of the object support means extends generally longitudinally of the housing and is capable of supporting a plurality of objects. Thus, according to the first embodiment, object support means resembles an elongated peg or rod which suspends objects from holes or perforations provided therein. . . The longer leg of support means also desirably is formed with a raised portion to prevent the objects from unintentionally sliding off the object support means.
>
> It will be appreciated that hook register finds beneficial usage with articles or objects which are suitable for suspension and whose inventory it is desirable to monitor. Typical items may include packages containing medical items such as drugs, medical equipment, supplies, including for example, catheters and guide wires for angioplasty or other medical items which should be strictly and accurately monitored because of theft, safety, critical need or other concerns. For this reason, the object support means may assume any form necessary or desirable to support the objects supported thereby. That is, the object support means may

be configured as a rack, multiple hooks or pegs or similar cantilevered members, a tee bar or other such equivalent constructions. (col. 6, lines 13-54)

In another embodiment of the invention in the '046 patent not cited by the Examiner, there is provided:

> [an a]pparatus. . .called a box register as it is optimally adapted to include storage locations for holding boxes or box-like articles. Box register includes an elongated housing including an upper wall, a lower wall, end walls, a front wall and a rear wall. Like housing of hook register, [this] housing may be fabricated from any durable material such as plastic or metal. Although not shown, it will be understood that a clip assembly. . .or a similar attachment mechanism may be used to detachably fasten the housing to a wall. Alternatively, apparatus may rest on a level shelf, tabletop or reside in a cabinet....
>
> With regard to the box register, in this embodiment, an object support means. . .which. . .may assume the form of a receptacle having at least one or preferably a plurality of compartments or object storage sites which are locations wherein medical items may be stored. In this embodiment, object support means is constructed as a multiple compartment, heavy gage, stiff metal wire rack including a pair of upright truss-like end walls, a plurality of spaced apart storage site divider walls situated between and generally parallel to the end walls and a plurality of transverse members affixed to the end walls and divider walls. The end walls are desirably secured by suitable mechanical fastening means, such as nuts and bolts or the like to lower wall (as shown) or any other wall of the housing.
>
> [T]he object support means is adapted to support objects of substantially uniform dimensions...in a substantially upright orientation. For example, objects may be generally uniformly sized relatively thin boxes or similar packages which may contain various designated types of medical products. The object support means as illustrated is thus capable of supporting an object on four sides thereof, i.e. the bottom, back and both lateral sides of the object....In this fashion, an object may be removed from the object support means by lifting it forward. . .and/or upward. . . .
>
> Although the described embodiment of the object support means supports the objects such as boxes in substantially upright or vertical position, the present invention also contemplates rack geometries whereby objects may be supported substantially horizontally, at acute angles or in a staggered array incorporating one or more angular support orientations. Further, the spacing between the divider walls need not be uniform in which case storage sites of variable dimensions may be provided in the same object support means. Of course the object support means, like housing, may be fabricated of metal or from any high strength substantially rigid plastic or other suitable material.

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> Although the box registers shown are a single tiered rack, the object support means may comprise a multi-tiered rack or a plurality of rows and/or columns of cubicals [sic] whereby each of the storage sites or cubicals [*sic*] may be appropriately fitted with a switch actuating means such as a lever. . .However, unlike the hook registers which may store a substantial number of units of the particular type of medical item in each location, a box register is adapted to store only one such item in each location. Therefore, in some embodiments several adjacent locations in the box register are designated for containing the same type of medical item. (col. 14, line 24 - col. 17, line 51, drawing reference numerals deleted)

Finally, the holder of the '046 patent uses the term "dispenser" or "storage location" in the claims to stand for the hook or box registers described in the specification. *See, e.g.,* claim 1 ("A system for dispensing medical items comprising: a dispenser, wherein said dispenser is selectively operable to dispense medical items...."). The distinction is further strengthened by the '046 patent holder's use of the term "storage location" in claim 18. The closest language to that of the term "container" as used in the claims of the present invention is found in claim 18: "A system for providing medical items for use by patients, comprising: *a storage location*, wherein medical items are stored in said storage location prior to dispense to a user for administration to patients...." (italics added)

In contrast, the present invention claims a container adapted to accept and store medical or surgical objects after they are used. Moreover, the sensor recited in the present claims is adapted to sense the medical objects when they are inserted into the container, not when they are removed as in the '046 patent.

Furthermore, the very nature of the container of the present invention and its contents is different from that claimed in the '046 patent. The dispenser of the '046 patent is directed either to articles or objects which are suitable for suspension, e.g., packages containing medical items such as drugs, medical equipment, or supplies such as catheters and guide wires for angioplasty,

or to articles or objects of substantially-uniform dimensions which must be held in a substantially upright orientation, such as generally uniformly-sized relatively thin boxes or similar packages which may contain various designated types of medical products. In contrast, the container of the present invention is directed to sponges, lap pads, pledgets, peanut sponges, cottonoids, needles, and clamps. These are medical or surgical objects or articles of varying shapes and sizes which need not be stored or contained in any special manner as determined by those shapes and sizes.

It is evident, therefore, that combination of the teachings of the two cited references would fail to produce the invention as claimed by Applicant.

When a claim of obviousness under 35 USC § 103 is based upon a combination of prior art references, there must be some suggestion or motivation, either explicitly in that reference or otherwise implicitly in the art, to combine those references to produce the claimed invention. *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastic, Inc.,* 75 F.3d 1568, 1573, 37 U.S.P.Q.2d 1626, 1629-30 (Fed. Cir. 1996). That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to make the claimed invention. *See Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301-2 (Bd. Pat. App. & Int'f 1993).

In this instance, the '086 patent and the '046 patent, both individually and combined, fail to suggest, either explicitly or implicitly, to one skilled in the art, methods and apparatuses for providing inventory control of used sutures, needles, lap pads, sponges, and other medical objects within a sterile operating room environment. These two patents also fail to suggest a system of surgical inventory control which eliminates manual counting methods to prevent accidental

enclosure in a patient and also reduces the hazardous handling of sharp objects. It is respectfully urged, rather, that the Examiner offers no showing of impetus in the '086 patent and the '046 patent or elsewhere which would lead one of ordinary skill in the art to modify the invention claimed in these patents to make the present invention. Thus, the Applicant respectfully submits that the present invention cannot be rendered obvious by the '082 patent in view of the '046 patent without the impermissible use of hindsight.

CONCLUSION

It is urged that this continuation application is in condition for allowance. Early and favorable action by the Examiner is therefore earnestly solicited. The Examiner is respectfully requested to telephone Applicant's undersigned representative at 212-848-1046 to arrange for a personal or telephonic interview in an effort to remove any impediments to the allowance of this application.

AUTHORIZATION

No fees other than that due for a continuation application is believed due. However, the Commissioner is authorized to make any other charges or credits to Greenberg Traurig, LLP's Deposit Account No. 501561.

Respectfully submitted,

Date: May 1, 2001

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